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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,309

04/16/2004

Richard S. Kusleika

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,309	Applicant(s) KUSLEIKA, RICHARD S.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/28/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-24, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3763

DETAILED ACTION

Response to Amendment

Amendment filed on 1/28/09 has been entered.

Claims 16-24, 38-39 are present for examination.

Claims 1-15, 25-37 are cancelled.

The Advisory Action mailed out 2/17/09 has been withdrawn because Examiner made a mistake.

Since this new rejection was necessitated by amendment, the present Office Action is made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-24, 38-39 are rejected under 35 U.S.C. 103(a) as obvious over Shockey et al. (US 4,994,033) in view of Sogard et al. (US 5,447,497).

Shockey discloses a process for treating tissue at a treatment site within a body lumen, comprising: providing an elongate flexible catheter 12 having a flexible treatment sheath 22 mounted to a distal end region of the catheter and a dilatation balloon 30 within the flexible treatment sheath, wherein the flexible treatment sheath is formed of a elastic material;

intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a treatment site (col. 3, lines 55-66); supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath (through the holes 28) to the surrounding tissue, and maintain the treatment sheath expanded into the contact (col. 3, line 55-col. 4, line 8); at this point, the treatment sheath 22 is expanded because the drug or other material is introduced; the treatment sheath 22 having

Art Unit: 3763

holes 28, therefore, it is inherently that some of drug or other material introduced into the lumen of treatment sheath will exit out through the holes 28 and delivery to target sites. At this times, the dilatation balloon 30 stills in unexpanded condition;

while maintaining the treatment sheath in the substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon 30 within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue (col. 4, lines 8-29).

Shockey does not disclose the dilation balloon 30 is formed of a substantially inelastic materials.

Sogard discloses a similarly device comprising an elongate flexible catheter 20 having a flexible treatment sheath (outer sheath) 26 mounted to a distal end region of the catheter and a dilatation balloon (inner balloon) 28 within the flexible treatment sheath 26, wherein the flexible treatment sheath 26 is formed of an elastic member, such as high-compliant balloon are made from soft or flexible polymeric materials (col. 2, lines 28-40, col. 8, lines 30-31); and the dilatation/inner balloon 28 is non-compliant balloon are made from inelastic materials such as rigid or stiff polymeric materials (col. 2, lines 43-52, col. 8, lines 49-50).

As noted that Applicant acknowledge that the inelastic materials such as PET, polypropylene (see page 2 of Pre-Appeal Brief filed 7/28/08) are similar to materials that Sogard discussed in col. 2, lines 43-52, col. 8, lines 49-50.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Shockey with a dilatation balloon made of an inelastic material, as taught by Sogard, in order to dilate and prevent the rupture of balloon since the small increase in diameter when the balloon inflated to its expanded diameter

Regarding claim 19, a guide wire 18 with a distal end thereof outside of the body, inserting the proximal end of the guide wire lumen running through the catheter, and advancing the catheter distally relative to the guide wire.

Art Unit: 3763

Regarding claims 20-21, the supplying of the treatment fluid comprises causing the treatment fluid to perfuse through the pores 28 in the treatment sheath.

Regarding claims 22-24, the dilatation balloon 30 radially enlargeable by supplying a dilatation fluid to a dilatation chamber formed by the balloon and the catheter, wherein the contraction of the dilatation balloon comprise withdrawing the dilatation fluid from the dilatation chamber to substantially evacuate the dilatation balloon (col. 4, lines 10-30); allowing the treatment sheath to radially contract comprise withdrawing the treatment fluid from the compartment through the pores 28; allowing a flow of body fluids through the catheter past the treatment site (col. 4, lines 15-23).

Regarding claim 38, the treatment sheath 22 is formed of a biocompatible elastomeric material such as a thermoplastic elastomer (col. 3, lines 12-16. Furthermore, it is well-known in the balloon art to made of materials in claim 38.

Regarding claim 39, Shockey in view of Sogard fail to disclose that the biocompatible elastomeric material has a modulus of electricity in range of 2,000 to 80,000 psi; the sheath has a thickness in the range of 0.5-5 mils. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the values list in claim 39, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to claims 16-24, 38-39 have been considered but are moot in view of the new ground(s) of rejection.

Please see the explanation above for more details.

Art Unit: 3763

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763